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                     UNITED STATES DISTRICT COURT
                    FOR THE DISTRICT OF NEW JERSEY
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                                   CIVIL ACTION NUMBER:
    IN RE: VALSARTAN PRODUCTS
    LIABILITY LITIGATION
                                   19-md-02875
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                                   CASE MANAGEMENT CONFERENCE
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         Mitchell H. Cohen Building & U.S. Courthouse
         4th & Cooper Streets
 8
         Camden, New Jersey 08101
         July 28, 2022
 9
         Commencing at 10:01 a.m.
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    BEFORE:
                             THE HONORABLE ROBERT B. KUGLER
11
                             UNITED STATES DISTRICT JUDGE
12
                             THOMAS I. VANASKIE (RET.)
                             SPECIAL MASTER
1.3
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               produced by computer-aided transcription.
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    ALSO PRESENT:
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         LORETTA SMITH, ESQUIRE
         Judicial Law Clerk to The Honorable Robert B. Kugler
 3
         Larry MacStravic, Courtroom Deputy
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             (PROCEEDINGS held telephonically before The Honorable
 2
    ROBERT B. KUGLER and SPECIAL MASTER THOMAS I. VANASKIE at
    10:01 a.m.)
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             THE COURT: Judge Vanaskie, are you on board?
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             SPECIAL MASTER VANASKIE: Yes, I am, Judge Kugler.
 6
    How are you doing?
 7
             THE COURT: Fine and dandy, enjoying the summer.
 8
             Okay. Look, there's a number of issues that we want
 9
    to talk about today.
10
             Let's start with the easy part. Mr. Harkins, are you
7 7
    on the phone? Mr. Harkins?
12
             MR. HARKINS: Yes, Your Honor, I'm here. This is
13
    Steve Harkins with Greenberg Traurig for Teva and the joint
14
    defense group.
15
             THE COURT: Do you want do that paragraph 3 of the
16
    defense letter, we'll talk about?
17
             You apparently -- on the 12 orders to show cause, you
18
    want to dismiss half of them, the other half you want to move
19
    to next time; is that correct?
20
             MR. HARKINS: Yes, that's correct, Your Honor. There
21
    was one update.
22
             We will also agree to withdraw number 6, William
23
    Davis, and then just carry the five others that we noted in
24
    our position statement forward for another month.
25
             THE COURT: Okay. Let's do that then.
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             As to the pending orders to show cause, the Payne,
 2
    P-A-Y-N-E; Callahan; Anderson; Walker, Williams; and White
 3
    cases, those orders to show cause are dismissed.
 4
             As to the Shemes, S-H-E-M-E-S; King; Tolley; Peyton;
 5
    Branch; Vindigni, V-I-N-D-I-G-N-I, those matters are carried
 6
    for a month and would appear on next month's order to show
 7
    cause list.
 8
             And that leaves five -- four new ones to be listed
 9
    for next month, orders to show cause.
10
             Estate of Robert Cooper v. ZHP, that's the Levin
11
    firm.
12
             Anybody want to speak on that matter?
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             MR. NIGH: Yes, Your Honor. We don't have any
14
    objection to entering an order to show cause. I just would
15
    say that our missing thing is medical billing. We don't that
16
    really rises to the standard of a core deficiency, but I think
17
    we can have that battle next month if for some reason we can't
18
    still get that medical billing.
19
             THE COURT: Okay. Thank you.
20
             That will be listed for an order to show cause.
21
             Number 2 is Raymond Dais, D-A-I-S. That's the Dennis
22
    F. O'Brien firm.
23
             Anybody want to speak on that matter?
24
             (No response.)
25
             THE COURT: Nope, okay. That will be listed for
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    dismissal next month.
 2
             Third is Elie, E-L-I-E, Greene, G-R-E-E-N-E. That's
 3
    the Serious Injury Law Group.
 4
             Any want to speak on that?
 5
             MS. JONES: Yes. This is Joanna Jones on behalf of
 6
    Gerald Brooks. The update is really the same as last week.
 7
    We've hired an attorney to open up the estate, so we're just
 8
    kind of waiting on the estate to be opened up so we can
 9
    proceed.
10
             THE COURT: Okay. Well, we have another month to try
11
    to work that out. If not, then you can always talk to
12
    Mr. Harkins before next month to try to carry it again. Okay?
1.3
             And then there's Marjorie Smith as administrator of
    the estate of Erskine Smith.
14
15
             Anybody want to talk on that?
16
             MS. JONES: Yes. This is Joanna Jones again.
17
             The plaintiff fact sheets have been amended to fix
18
    the errors. Also appropriate authorizations were filed this
19
    week. The only things that we're missing is the mental health
20
    records that were requested, and we have requested those,
21
    we're just waiting for them to come in.
22
             THE COURT: Okay. Well, you've got another 30 days
23
    to try to work that out with Mr. Harkins. But we'll list that
24
    for next month's orders to show cause. Okay?
25
             MS. JONES: Thank you.
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             THE COURT: Then there are ten cases that Mr.
 2
    Harkins -- the defense has listed to be relisted.
 3
             Any updates on those, Mr. Harkins?
 4
             MR. HARKINS: Yes, Your Honor, a number of updates.
 5
    We can remove number 1, Connie Keep; number 2, Sandra Russell;
 6
    number 7, Frances Cain; and number 10, Carrie Collins. And
 7
    the rest of the cases would be just carried forward for
 8
    another month.
 9
             THE COURT: Okay. Then that will be number 3, Debra
10
    Stiles, S-T-I-L-E-S; number 4, Jim Smith; number 5, Frank
11
    Trimboli, T-R-I-M-B-O-L-I; number 6, Audrey Dequeant,
12
    D-E-Q-U-E-A-N-T; number 8, Walid Elganam, E-L-G-A-N-A-M; and
1.3
    number 9, Richard Wilson. Richard Williams, I'm sorry.
                                                             We'll
14
    list those for next month again for another listing.
15
             All right. Let's get right to the case management
16
    issues that are raised, the dispute between the plaintiffs and
17
    the defendants about trying to figure out the third-party
18
    payor, TPP, case to go to trial in this case.
19
             And defense has raised a number of issues, some of
20
    which need to be discussed.
21
             I'm not concerned about the entire controversy
22
    doctrine. That wouldn't prevent me under Rule 21 to sever
23
    certain granting parties.
24
             Class certification motions, that is an issue because
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    of one-way intervention.
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We are working on those, folks. They're a lot of
work, but we are working on them. And we hope to have them in
the not too distant future resolved.
         But that leaves I think a really difficult issue that
we have to talk about, the trials. And that's the Lexecon
problem.
         Now, I haven't seen any waivers from any defendants
that would permit me to try any of these cases, and I think
Lexecon implicates the plaintiffs' proposal here. So that's
an issue that needs to be addressed.
         And the personal jurisdiction issue that was raised
by defense counsel was addressed sort of two days ago by the
Third Circuit in that Fischer case, that opt-in FLSA case with
the out-of-state plaintiffs. So that continues to be a bit of
an issue. That has to be resolved.
         Who's going to speak for the plaintiffs on the
Lexecon problem, if anybody?
         MR. HONIK: Good morning, Your Honor. This is Ruben
Honik. I'll be addressing the case management issues.
         THE COURT: Okay. What are we going to do about the
Lexecon problem?
         MR. HONIK: Your Honor, I understand how the issue
has been framed, but the defendants have really cited nothing
that prevents the Court from certifying consumer or TPP
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classes and subclasses, adjudicating summary judgment and

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    pretrial motions, and then severing and remanding cases to
    transferee courts. That's point number one.
 3
             Point number two, perhaps even more important, is
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    that at least one named plaintiff in each of the two proposed
 5
    trial groupings have originally filed complaints in the
 6
    District of New Jersey, meaning that this court already has
 7
    jurisdiction and venue over an original action that doesn't
 8
    require transfer.
 9
             And for the record, that would be the Brian Wineinger
10
    case which was filed before you, Judge, against Solco and
11
    Prinston.
12
             That permits you to proceed at the least as to that
1.3
    case without a waiver, and therefore, I don't believe Lexecon
14
    is implicated.
15
             THE COURT: Was the Wineinger case, was it filed as a
16
    result of a direct filing order, or was it filed independent
17
    of your direct filing order?
18
             MR. HONIK: My best --
             THE COURT: I mean, should it really be in New
19
20
    Jersev?
21
             MR. HONIK: Yes, Judge, it really should be in New
22
    Jersey. And unless someone can correct me from our team, that
23
    was originally filed in New Jersey before you at 19-cv-01070
24
    in April of 2019 against defendant subsidiaries in New Jersey.
25
             So that case is I think teed up and ready to go with
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Is that what you're saying?

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MR. HONIK: That's right, Judge. And just to take a half step back and maybe frame the discussion that might be useful, when the cert briefing was complete, it certainly occurred to the plaintiffs that we needed the Court to step in and provide some case management direction for merits and expert reports and dispositive motions. And that went directly to what you conveyed to the parties correctly, which is we've got to keep this case moving.

And as both Judge Vanaskie and you are aware, we have proposed a schedule. We conferred with the defendants. It was somewhat modified and tacked on an additional 60 days because of some protestation by the defendants.

And we now have Case Management Order Number 28, which has been docketed. And we have a timetable for the exchange of expert reports and dispositive motions with the hope that we're going to have an economic trial of some sort in the very near future to move this case along.

And the defendants, faced with this case management order and an expression from us that plaintiffs, we in fact were going to pursue dispositive motions, complained that it was untethered, that was the very word they used repeatedly at our last conference, untethered to any particular claim, any particular defendant, any particular plaintiff.

And we responded, just as we said we would to Judge Vanaskie over a week ago now. And we proposed what we think

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is the most sensible management grouping possible in proposing a first consumer class based on warranty, both implied and expressed. The defendants now know precisely which defendants we'd like to go after first in a trial, namely, ZHP, Teva and Torrent.

The reason Teva and Torrent are in, because they use ZHP API. They're very significant defendants in this litigation, as everyone well knows. And in many respects, the warranty claims and the consumer warranty claims are among the very straightforward, most streamlined of claims possible that can be tried. They implicate every one of the legal and factual issues that implicate the bodily injury claims.

And we were very mindful in proposing it. We think too that dispositive motions can clearly be filed on warranty, because the Court has shed considerable light in its Rule 12 opinions about how the warranty analysis should apply here.

And so when it's all said and done, we think because of the alignment between consumer economic claims and consumer BI claims, among all the possible grouping choices, that presents the greatest efficiency.

And let me say, Judge -- and we attached this as an exhibit to our reply brief in our cert briefing -- the Federal Judicial Center really provides guidance that is very much in line with what we've proposed.

If the Court were to look again or refresh itself on

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1 an excellent primer that the Judicial Center has authored in 2 2018 called Managing Related Proposed Class Actions of Multidistrict Litigation, one would find on page 5 the very 3 4 topic that we're talking about today, namely, how to group for 5 motion practice and discovery and for trial. 6 And if I may, the guidance from the Judicial Center 7 says, and I quote: "Typically cases are split up by plaintiff 8 type, but judges' creativity in meeting the challenges 9 presented by multiclass MDL proceedings is unlimited." 10 That's in the text, not my word. 11 "Cases" can "be split up by the nature of the claims 12 brought...or by time of filing. Plaintiffs" can "be grouped 1.3 based on whether they have opted out of arbitration or not. 14 In antitrust proceedings, cases" can "be grouped based on 15 which subset of defendants is being sued." 16 And the guidance goes on to give illustrations in 17 both the complexity of the task but how grouping can

facilitate litigation.

And it cites, for example, Judge, the Blue Cross Blue Shield Antitrust Litigation. And it's very instructive here.

There in that litigation there were two tracks. There were subscribers and providers, which are roughly analogous to direct and indirect purchasers, and within each track there are multiple alleged classes divided by regional market.

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Now, if we stop for a second, that very example is precisely what we have here. Completely analogous to indirect and direct purchasers, subscribers and providers is what we have in the form of consumers and TPPs.

Here the direct purchaser is really the consumer. They're the ones that got the warranty in their hand. a slight difference in that analysis when we get to the TPPs, because they simply paid for a part of the purchase. But the consumer stands in the exact position of a direct purchaser in an antitrust case. And that is among the reasons that we really proposed that as an initial class trial to proceed and to work up in the way of dispositive motions.

That really will engender and encompass and implicate the greatest number of common issues, both legal and factual, on both the BI side and the economic side, whereas the TPP has certain wrinkles in it that I think makes it not entirely sui generis, but not as aligned as a consumer economic class, as a BI class.

Now, let me conclude by saying the plaintiffs stand absolutely prepared, Judge, to work up for trial or toward trial any grouping that the Court desires. And in fact, the Court has tremendous flexibility in terms of sequencing and as has been done by, among others, Judge Weinstein in Zyprexa, more recently in the Juul case.

You're even at liberty to issue tentative rulings

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both as to summary judgment, as to class and so forth, to provide guidance to the parties about how to proceed to tee up the issues in this case.
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And so, you know, we hope and implore the Court to consider our proposal which encompasses major defendants, common facts on both the BI track and the economic track by suggesting a consumer warranty class as the first case to go. But I dare say if the Court decides, for example, that we're not going to do ZHP, we want to do Hetero first, that's fine too. If the Court directs that we do a TPP class trial first, it's -- after a certification ruling, we're prepared to do that.

But we think in the best of all worlds, a consumer class based on warranty is the cleanest. We can narrow it down even further by dispositive motions. And I think it will be the biggest, if you will, legal bang for the buck in terms of moving this case forward towards some sort of resolution.

THE COURT: Mr. Trischler, you signed the letter. Do you want to speak on this, or do you have someone else who is going to speak on this?

MR. OSTFELD: Good morning, Your Honor. This is Greg Ostfeld. I'll be speaking on this issue on behalf of the objecting defendants.

THE COURT: Okay. Great, thank you.

MR. OSTFELD: Your Honor, I certainly appreciate

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Mr. Honik's presentation on this. And with due respect to him, it sort of feels like we're going backwards a little bit.

The Court already exercised its creativity in accordance with the guidance of the Judicial Center at the June 1st hearing. And we took the Court's guidance to heart and agree with the Court that the first economic loss trial should be relatively straightforward and should not be piecemeal.

And we feel the Court was fairly clear, you indicated that we should for purposes of this first trial -- and we took the goal to be setting a case that could proceed to trial, not towards piecemeal proceedings. The goal should be to focus on the third-party payor economic loss cases.

And as Your Honor prudently noted, the reason for that is because those cases are likely to go forward irrespective of the outcome of the forthcoming class certification ruling. It doesn't require a predisposition or an assumption as to how the Court is going to rule and what it's going to do with the class certification rulings. It doesn't require us to go through the Rule 23(f) review process. It doesn't require us to define the parameters of the classes, you know, what they're going to do, or guess at what they're going to be. We can simply proceed to work up a third-party payor, which is what the Court indicated it would like to see done, and to advance it towards trial.

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Whatever the merits of Mr. Honik's proposal, and we have a lot of disagreements with them, it is a certainty that that will be a piecemeal proposal. It will not be relatively straightforward. And it cannot lead to a single trial.

And the reason for that is it involves 12 plaintiffs from 10 states. It involves 48 proposed subclasses. It involves 28 jurisdictions.

Putting aside the many reasons we have indicated why that is not workable at all as a class certification proposal, it is certainly not triable before this Court.

As Your Honor noted, there are personal jurisdiction and Lexecon issues. Some of the defendants are subject to this Court's general jurisdiction. Many of them are not. And Your Honor to this point has declined to hear personal jurisdiction motions. But if the time comes where we start to work up a case for trial, it will certainly be time to hear those personal jurisdiction issues, which the Court expressly reserved to this point.

There are multiple foreign defendants who have never had their personal jurisdiction arguments heard. There are also a number of plaintiffs who are from out of state who either direct filed into this court or filed in other states. There have been no Lexecon waivers.

So it is a certainty that the path that Mr. Honik has proposed cannot lead to a single, simple, straightforward

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trial before this Court. It can only lead to a jumbling of proceedings, a mélange of proceedings which we take to be inconsistent with the Court's preference. What the Court wants us to do was set aside, as Your Honor put it, the obsessive focus on these class action motions, proceed to a third-party economic loss case, identify one that can be tried and move that. Your Honor said that we don't want to piecemeal these things. And what we're going to be doing here most certainly would be piecemealing them.

The plaintiffs have not proposed to just put

Mr. Wineinger's case before the Court and put that on a trial

track, they proposed to put 12 plaintiffs' cases before the

Court. And it is not possible to do with that what the Court

wants to do, which is try to move, to really advance the

ultimate termination of this litigation, to get some guidance

from a trial that can then inform the parties with respect to

settlement, with respect to the course of future classes.

It is not a simplifying procedure the plaintiffs are proposing. They are proposing a complicating procedure, one that is going to spin off in hundreds of different directions, one that may have to be put on pause if there is a Rule 23(f) review by the Third Circuit, one that could be rendered futile if Your Honor denies class certification or moves in a different direction than the parties are conjecturing the Court may go. And it would just be a guess or a conjecture at

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this point. That is really the one-way intervention problem.

We understand and appreciate that the Court is working hard on those class certification rulings. And it's a large task, and we certainly don't begrudge the Court the time it will take to do that.

But until it is done, we do have a one-way intervention problem. We have a problem of cases proceeding on the merits in such a way that would enable class members to wait and see how it goes and then decide whether or not they're going to get involved or not.

And, Your Honor, we certainly understand that Your Honor can sever cases, that you can solve the entire controversy and claim preclusion and claim splitting issue by severing cases, but plaintiffs right now are proposing to work up specific claims on behalf of the same named plaintiffs while leaving others on the sidelines.

And while Your Honor can certainly solve the entire controversy and claim splitting issue by having all of one plaintiff's claims severed out and tried in one proceeding, we respectfully do not think that Third Circuit precedent would allow an individual plaintiff's claims to be split into multiple proceedings and multiple trials arising -- against the same defendant arising out of the same event.

So respectfully, Your Honor, we think the goal should be to get back on track, get back to the mission Your Honor

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of that nature.

articulated at the June 1st hearing and move towards a single plaintiff/third-party payor trial that can be tried as a discrete, non-piecemeal proceeding and that would materially advance the ultimate termination of this litigation.

This is putting the cart before the horse, Your Honor. To proceed on this before Your Honor has entered a class certification ruling, to proceed on a class claim until Your Honor has ruled on class certification and until the Third Circuit has at least been given the opportunity to say whether it is going to weigh in would be putting the cart before the horse.

THE COURT: Thank you.

Mr. Honik, I get where you're going with all this.

And it's a good effort, but I still believe that the best way to proceed to the first trial is a single TPP plaintiff, which

MR. HONIK: Your Honor, here's how we see the problem with that approach.

implicates, you know, only maybe a few states' laws and things

The TPP plaintiffs in this case have a fully briefed motion for class certification before you on behalf of a class. To try either MSP or MADA's individual claims while that motion for certification is pending would bring about ironically the very one-way intervention that defendants claim they are seeking to avoid.

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The -- respectfully, the MSP and MADA class members are entitled to have a ruling on their cert motion before there's a review of their merits in a trial or other proceeding. And by doing otherwise I think would violate MSP and MADA's due process rights in the same way that defendants maintain theirs would be violated in the event of some substantive ruling as to their rights.

And I want to emphasize that at no time have we ever proposed that we proceed either on summary judgment, as to summary judgment, or a trial before the Court has an opportunity to weigh in on one or more of the proposed classes. We think the proper sequencing — and the Court has alluded to it — is to have at least some ruling, even if it's not a dispositive ruling, can be, you know, an informative ruling to us, but likely a final ruling on one or more classes, followed by a notice period during which the parties have put on your desk, Judge, dispositive motions to narrow the issues as we get closer to trial disposition, motions in limine and the like, and then get ready to proceed.

And certainly if after that process Your Honor feels that the TPP class is the first one to go, we're ready to go and we'll do it.

The reason we proposed a consumer class is because we believe in the best of all worlds. Both the legal and factual issues of consumers as the -- essentially the direct

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purchasers here really implicate the greatest number of issues for a factfinder to determine.

That is not entirely true as to TPPs, because as Your Honor knows, they weren't handed this prescription. They didn't have the label. They didn't consume this drug, which created an increased risk of an adverse health effect, and as to our BI clients actually created an adverse health effect. So we think in the best of all worlds, a consumer economic class is the one that really implicates the greatest number of issues.

And let me just add further that there's a lot of skin in the game with the economic class. The class that we proposed, strictly the ZHP/Teva/Torrent express warranty and implied warranty groups -- which, by the way, all of the states that we've grouped together have identical law. So this business, which is really a rehash of their opposition to our cert motion, is really without air.

But putting that aside for the moment, we're talking about damages that have been modeled in excess of \$100 million. That's strictly for warranty, strictly for Teva, Torrent and ZHP. And we think that that would be a very meaningful first trial which would implicate the greatest number of issues, including legal issues for the TPP, but the consumers are the ones that were the direct purchasers here.

The guidance from the Federal Judicial Center clearly

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speaks in the MDL and particularly the antitrust setting of having the lead cases be the direct purchasers, indirect purchasers, or the providers coming after the subscribers.

Document 2142

The concept there, Judge, is that that's where the rubber met the road. Our consumers were the ones that went into these pharmacies, were told they were buying valsartan and didn't get valsartan. And we think that summary judgment on warranty will further narrow the issues and present the cleanest, most efficient way to proceed, and frankly, to expose the parties to enough skin in the game that could potentially globally move toward a resolution of the entire litigation.

THE COURT: I'm not sure having a trial with the most possible issues moves us as quickly as we need to to the final resolution of this case, to be honest with you. I understand what you're saying, because it does put pressure on the defendant to face a consumer case where you have actual people talking about their prescriptions and the stakes being, as you say, \$100 million or maybe more.

But I still think the question we need to have answered or seem to need to have answered is whether or not this stuff was contaminated and whether it was worth anything, you know, to the purchasers or anyone else who paid for it.

And I think the easiest way, the fastest way to get there is a TPP single plaintiff case, to be honest with you. I continue

to believe that.

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MR. HONIK: Your Honor, I understand that. I took to heart many of your comments before today about the value of bellwether personal injury cases. And I happen to share your view about them. But I think that's what we would be engendering by having an isolated TPP case.

So let's say we tee up MADA's individual claim here in order to hopefully tease out some specific issues that really do cut across all the claims here.

If MADA were to lose their individual trial, it wouldn't dispose of anything. MSP would still have claims. And obviously there would be the issue of class certification for TPPs. There may be any number of individualized reasons why MADA, just to use an example, might not prevail in a sort of bellwether trial.

So in my view, in our view, Judge, as we really spent time thinking about this, effectively having a single bellwether isolated trial for one TPP not only I think potentially involves due process issues when there are pending motions, but as a practical matter, it doesn't really move the needle or potentially won't move the needle, because if -- in my hypothetical, if MADA were to lose it, it's just like losing a BI bellwether trial. We move on to the next one. And I think that that will prolong the litigation.

I think in the best of all worlds, respectfully, if

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the Court is presently honing in on, you know, considering our certification motion, whether as to all of the proposed classes or even just one subclass, namely, warranty for ZHP/Teva/Torrent, to me, that really -- that really produces a big bite.

And again, we reiterate that we're prepared to do any combination or any grouping that the Court wants. If you want a smaller bite with Hetero, just for example, we're happy to do that. But we think going in the direction of consumer economic class issues really is the way to go, because it's nonspecific. It has no individualized issues that they
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THE COURT: Well, what happens if you lose your consumer case, now where are we?

consumer who really is the direct purchaser here.

pertain to someone paying for a prescription rather than the

MR. HONIK: Then there's preclusive effect. We've rolled the dice on a class-wide basis for the economic group, and we've lost on the warranty claim.

And if you severed out, which is your right to do, and it's done all the time by transferee judges, if we do just warranty, then the next trial it can be with the same jury, we look at the fraud issue. But we think that the warranty issue is the first big one to go. And if we lose it, to answer your question, then it's preclusive as to the economic claims based on warranty.

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1 MR. OSTFELD: Your Honor, this is Greg --

THE COURT: -- very much, to be honest with you. If you lose that one, I don't think it's -- I don't think we're any worse off if we lose that one than we would be if we lose the TPP individual case in terms of where we end up down the road with all these cases.

MR. HONIK: Well, I take your point, Judge, but I really do believe that we have a one-way intervention problem, not with what the defendants are concerned with but by picking out an isolated TPP individual claim when there is already a pending motion to certify a class.

And that directly implicates the one-way intervention problem that the defendants are complaining about, which frankly don't exist for them but I think would be a present problem for either MSP or MADA who, you know, have and should have a full and fair opportunity to be heard on their Rule 23 motion to certify a class of which they're a member.

THE COURT: They're going to get the opportunity to be heard on class motions. Like I said, we are endeavoring to get those done and we will get them done. It just takes time to get this stuff done.

Anyway, thank you, but I'm not convinced that we need to go that route that the plaintiffs are suggesting, the consumer route. I still believe we're going to go through with the TPP individual trial first. That will be the first

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    trial.
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             I'm not suggesting we want to do this tomorrow,
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    folks. There's a lot to be done yet. But that's -- I
    continue to believe that that's the best way to head this case
 5
    to final resolution.
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             I think simple is better, to be honest with you.
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             Anyhow, that's where we are. If you want to get
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    together, folks, and try to find an individual TPP plaintiff
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    and make a proposal to me at the next meeting, that would be
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    great. If not, then, you know, I'll do the work and I'll find
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    that and set that up for the first trial.
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             I think that leaves one more issue that were raised
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    in the papers.
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             Judge Vanaskie, were you going to handle this or do
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    you want me to handle this?
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             SPECIAL MASTER VANASKIE: Are you referring to the
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    CVS matter?
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             THE COURT: Yes, sir.
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             SPECIAL MASTER VANASKIE: Yeah. That was up to you.
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    If you want me to handle it, I'll be happy to handle it, but I
21
    wasn't sure.
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             THE COURT: If you want to do it, go ahead.
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             SPECIAL MASTER VANASKIE: Well --
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             THE COURT: Why don't do you it.
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             SPECIAL MASTER VANASKIE: Let's hear from counsel
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an independent medical monitoring cause of action were not

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allowed under Maryland law under this Court's prior ruling.

So there's no Maryland claim against pharmacies. So Celeste Daring doesn't have any claims and hasn't pleaded any claims.

By the way, as an aside, for the first time ever, plaintiffs mention Robert Fields in their CMC statement, although they didn't quite explain why. And we were quite confused, because Robert Fields filled his valsartan scripts at ShopRite and Giant, not CVS.

But regardless, like Celeste Daring, Robert Fields is a Maryland resident. And Maryland residents don't have claims against pharmacy defendants.

So there are no plaintiffs with claims against CVS who actually named CVS in the paragraph where they discuss where they filled their prescriptions.

And likewise, again, later in the medical monitoring complaint, when plaintiffs specifically discuss CVS, they do not identify any plaintiffs with current claims against CVS. They identify the three plaintiffs who have since dismissed their claims against CVS. And they identify Daring, the Maryland resident who does not assert any causes of action against CVS.

And I don't think plaintiffs dispute any of that.

Instead, they're grasping at straws and they're relying on an unasserted claim. And that's a claim belonging to Sarah Zher.

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It's not asserted and it's not pleaded, and that's the issue that I think is really important here, is what's the scope of the pleadings.

In the paragraph of the medical monitoring complaint discussing Zher, plaintiffs identify ZHP as having manufactured the valsartan she took. They identify Aurobindo as having facilitated the regulatory approval of that ZHP product. They allege that at least some of the products -- some of the ZHP product Zher purchased was purchased from ZHP by McKesson who in turn distributed this ZHP product to defendant Walmart and other retail pharmacy defendants.

That's it. That's all they say. There are no allegations relating to other manufacturers, no allegations relating to other wholesalers, no allegations relating to other pharmacies.

Plaintiffs are correct that CVS knew that Zher filled one 18-day script at CVS. Zher identified that script in her plaintiff fact sheet. She discussed it at her deposition. But that script was manufactured by Hetero as plaintiffs state on the fact sheet and as identified by the NDC code.

And I think it's interesting, in their position statement plaintiffs point to the language that a wholesaler sold this ZHP product to defendant Walmart among other retail pharmacy defendants as indicative that CVS was on notice of Zher's claims.

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But that 18-day fill plaintiffs are talking about involves Hetero valsartan, not ZHP valsartan. CVS didn't prepare a DFS for Zher, a fact, by the way, that plaintiffs never complained about.

So at this point, I don't know what role, if any, a wholesaler played with respect to that 18-day fill, but it is completely illogical to suggest that because, according to plaintiffs, McKesson sold ZHP valsartan to Walmart and other retail defendants, that CVS knew that plaintiff had claims relating to a Hetero product that was filled at CVS.

The paragraphs in the complaint relate solely to ZHP and the stream relating to ZHP. It never mentions Hetero. It never mentions Camber. It has never mentioned CVS. And it's precisely because CVS knew that they're filled at CVS and plaintiffs didn't name it in the complaint that we were prejudiced here.

Were we supposed to call plaintiffs up and ask did they really mean to include CVS in the paragraphs about Zher?

We didn't because it was entirely logical to us that plaintiffs would not rely on the de minimis use of one 18-day fill to name CVS and Hetero and Camber in light of their own arguments regarding the lifetime cumulative threshold plaintiffs proposed in their complaint and attempted to establish through expert reports.

I don't want to get too much into the merits of the

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LCT, but we would have asked questions of plaintiffs' experts, potentially hired our own experts just to discuss de minimis usage, and we would have breached the issue at class certification differently had we known that Zher was bringing claims against CVS.

And to give you just a brief overview of why this matters, remember here that we're talking about medical monitoring. The claims here are that the dose of valsartan with the NDMA impurity is sufficient to put a plaintiff at an increased risk of cancer. And to do that, plaintiffs themselves say you need to have taken a sufficient quantity of valsartan.

Zher filled one 18-day script of Hetero-manufactured valsartan at CVS. That comes nowhere close to the LCT that plaintiffs themselves proposed. To meet that LCT sufficient to warrant inclusion in the class according to the inclusion criteria proposed by plaintiffs, a plaintiff would have needed to take 32 months, nearly 1,000 days, of Hetero active ingredient. Zher took 18 days. That's less than 2 percent of the LCT plaintiffs themselves would have proposed as being sufficient to establish a lifetime cumulative exposure to valsartan. Or to put it another way, it's 54 times the amount of Hetero valsartan she filled from CVS needed to meet the LCT.

In contrast, plaintiffs have proposed an LCT

1 requiring only six month ZHP API at the dosage that Zher took. 2 Zher easily crossed the threshold for ZHP's API, 3 having filled more than two years of valsartan with ZHP's API 4 at Walmart. 5 That's presumably why they named ZHP/Walmart/McKesson 6 in her paragraph in the complaint. Again, that's also why she 7 didn't name CVS, didn't name Hetero, didn't name Camber. 8 You know, plaintiffs may have some substantive 9 arguments about whether those 18 days of NDMA contribute 10 enough to warrant inclusion in the medical monitoring as 11 contrasted to the two years of ZHP valsartan Zher took, but 12 that is not the issue here. 1.3 We didn't get to brief that issue. We didn't get to 14 ask plaintiffs' experts questions about that issue. We didn't 15 get to discuss it in our brief, at our depositions, because we 16 didn't know plaintiffs were planning on relying on claims 17 brought by Zher for CVS because they never pleaded them. 18 And I suspect this is not a one-off issue, Your 19 Honor. And that further exacerbates the prejudice here. 20 Again, in their CMC statement for the first time, 21 despite multiple efforts from me to meet and confer with

Again, I mentioned earlier, Robert Fields did not fill at CVS, he filled at ShopRite and Giant. And in any

plaintiffs about this, they again grasp at straws and mention

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Robert Fields.

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event, as a Maryland plaintiff, he has no claims against any pharmacy defendant.

The CVS Records Service Center did produce records from ShopRite to Marker, the third-party record collection agent in this litigation. But CVS never filled a DFS and never produced records as a defendant in the Fields litigation.

Even the Records Service Center records produced to Marker specifically referenced ShopRite. And the proof of use that Fields submitted with his PFS is a ShopRite bottle.

File buys are very common in the pharmacy industry, where records are transferred from one pharmacy to another. That's what occurred here. That's likely why plaintiffs never questioned why CVS did not fill out a DFS for Fields and why plaintiffs never mentioned Fields to me in my repeated requests for a meet and confer.

But just to give this a little bit more clarity, I looked at the paragraph mentioning Robert Fields specifically.

The complaint paragraph in the medical monitoring complaint specifically mentions ZHP API sold the United States with the assistance of Huahai, Teva, and Actavis. Those are the only defendants mentioned in that paragraph. CVS certainly is not mentioned in that paragraph.

But the Fields PFS references CVS as well as other APIs other than ZHP. So there's a discrepancy between the

fact sheet and the complaint.

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But how is a defendant supposed to know that plaintiffs are pursuing claims against other entities mentioned in the fact sheet when there are very logical reasons why those defendants are not named in the Complaint? Maybe it's because of the de minimis issue with respect to a different API. Maybe it's because the fill was at ShopRite, not CVS. I don't know. But I do know that there is no way that I would know Robert Fields potentially intended to pursue a claim against CVS. I still don't know that. He's not.

I haven't gone through and compared every fact sheet to the complaint paragraph. And I don't think that's our burden. It's not something we should be doing. But I think plaintiffs are suggesting now that we and every other defendant should have done that.

Are we supposed to do that? How are we supposed to know if plaintiffs are targeting a defendant with respect to a plaintiff's claims if it is not mentioned in the complaint, especially when there are very real de minimis issues associated with the medical monitoring claims in light of the lifetime cumulative threshold that plaintiffs themselves proposed, and especially when plaintiffs have never explained how the LCT concept works in the combination of -- the context of a combination of active ingredients?

I think there are very serious due process issues

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here, and that makes this issue one that goes well beyond
Sarah Zher's individual claims because it relates to the scope
of the complaint.

Is every defendant supposed to scour the PFS and deposition transcripts for every putative class representative for mention of that defendant and then reach out to plaintiff and say, did you really mean not to include us in the complaint paragraph about this plaintiff?

If there's an individual medical monitoring claim, even if the class actions for a limited subclass were remanded to its home court, how would defendants know if they were involved in that particular suit other than through the complaint reference?

We did not press plaintiffs' experts regarding the de minimis issue relating to the LCT because we were not mentioned in the complaint for plaintiffs like Sarah Zher.

So at bottom, if the plaintiffs are -- if the parties are intending to engage in settlement negotiations, how could they do so if they don't know which individual claims are brought against which defendants?

You know, I'm going to wrap this up and emphasize that this is not a dispositive motion issue. I'm not arguing the merits. I'm not trying to. But the defendants, CVS in particular, do need to know, indeed, we're entitled to know, which individuals plaintiffs are bringing claims against which

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    individual defendants and what remains of those claims.
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             It's not a merits issue but an issue about what
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    claims are being asserted and the prejudice of what plaintiffs
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    are trying to assert through functionally an amended complaint
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    but not really an amended complaint and never seeking leave to
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    amend.
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             That's a huge problem. There's real prejudice to the
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    parties. And respectfully, Your Honor, we believe CVS is
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    entitled to dismissal from the medical monitoring complaint.
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             SPECIAL MASTER VANASKIE: The end of your argument
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    there certainly makes it sound like this is a dispositive
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    motion issue.
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             But let's hear from -- who's addressing this issue
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    for the plaintiffs?
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             MS. GEMAN: I am, Your Honor. Good morning. My name
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    is Rachel Geman, and I am with Lieff Cabraser Heimann &
17
    Bernstein speaking for the plaintiffs on this matter.
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             SPECIAL MASTER VANASKIE: Very well.
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             MS. GEMAN: Thank you.
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             Your Honor, I do agree essentially that CVS is
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    seeking a rather drastic remedy of dismissal despite being on
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    clear notice of claims against it and the absence of
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    prejudice.
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             I would like, if I could, to begin with a couple of
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rather dispositive admissions made by Ms. Kapke.

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She acknowledged both that she was on notice of
claims against it, claims against CVS. And just to take a
quick pause there, of course CVS has been in every complaint.
We have pages of allegations about CVS in the operative
complaint, including paragraphs 68 through 76, 488 through
497.
         But the point is, you know, they knew that there were
claims. And she also acknowledged that Ms. Sarah Zher, a
Florida rep who is entitled to bring an independent claim for
medical monitoring, is indeed an adequate class rep in that
she has met the threshold, meaning she took enough bad
valsartan to be at, you know, a seriously enhanced risk.
         So that almost could -- we could almost end with
that, but I would like to address all the points if I could
very briefly.
         SPECIAL MASTER VANASKIE: Just briefly.
         MS. GEMAN: I beg your pardon, sir?
         SPECIAL MASTER VANASKIE: Briefly, please.
         MS. GEMAN: Yeah, yeah. Okay.
         So the bottom line is that, you know, CVS knew that
Sarah Zher, as addressed in paragraph 13, took contaminated
valsartan and that -- and she got some from CVS. CVS was at
her deposition.
         The quick background process was that we just -- as
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we honed the class definition, we agreed for certain other

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plaintiffs that they wouldn't be class reps, but it doesn't mean for purposes of a complaint that they were, you know, not properly in the complaint or not properly noticed.
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I want to speak about the prejudice. It seems that we're trying to combine or conflate notice issues with Rule 23 issues.

The complaint and the class cert motion were 100 percent clear that if some took a combination of valsartan, contaminated valsartan, it doesn't have to be one manufacturer, the point is, the relevance is if you have enough to be at the enhanced risk. So this notion that the so-called de minimis nature of her having taken CVS somehow detracts from the notice of the claim against them is without merit.

CVS -- none of the defendants opposed -- in their brief, CVS said we would have ask the expert questions and we would have challenged her adequacy.

First of all, none of the class cert defendants could or would have attacked the adequacy in our case.

If Your Honor looks at the class cert opp, they don't even mention Rule (a)(4), not at all, because these adequacies are relatively low threshold. These folks don't have conflicts and they took the medicine and their claims and it's tied up with typicality. There's no question that she's typical. The fact that she took a little or a lot via CVS

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doesn't matter. The point is CVS was alleged to engage in the misconduct we've alleged, and we have at least one plaintiff that ties it to it. I don't believe there would have been a separate adequacy brief about this one plaintiff when this was not an argument for anyone else.

With respect to the experts, as you know, there was -- the experts spoke about the feasibility of a monitoring program and the pricing of it. Not one of them on either side went into specific issues about, you know, if somebody took like, you know, 80 percent to get them to the threshold of X and 20 percent of Y. It doesn't matter for what the experts did. It's irrelevant.

So, you know, respectfully, I don't think there's any prejudice here. I think the stated prejudice seems to be an after-the-fact attempt perhaps to inject new arguments that weren't in the record, even though there are plenty of class reps, not just Ms. Zher, who like Ms. Zher took, you know -- essentially satisfied the class definition through long-term use of valsartan, which foreseeably means you might be at a couple different pharmacies, there might be a couple different APIs.

In short, we respectfully believe that the drastic remedy of dismissal is inappropriate given that we have this plaintiff.

You know, ideally would there be another clause or

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really -- especially given Ms. Kapke kept mentioning sort of
due process. I mean, we just want to underscore that the
extent to which CVS at large knows that there are claims
against it in its capacity as a retailer and these claims are
by both the independent monitoring class and the remedy class,
and so there's just no surprise here. There's no surprise,
there's no prejudice.
         SPECIAL MASTER VANASKIE: Anything else on this issue
on behalf of CVS?
         MS. KAPKE: I just want to follow up and say the
reason that the experts were not asked about the -- as
Ms. Geman put it, the 80/20 percent de minimis issue is
because it didn't come up in the complaint.
         I would have asked those questions of the experts.
We had several experts related to the LCT specifically, none
of whom had claims against CVS where there was a CVS plaintiff
who had less than 1 percent of the LCT compared to another
fill. And that's what we're talking about.
         There really is significant prejudice here, because
there's not an issue -- the LCT issue and the de minimis issue
was not teed up. We never got the opportunity to tee that up.
         And I do think that there is a significant typicality
and adequacy issue when you have a plaintiff who is going to
have to litigate whether there is a de minimis issue.
         Nobody has briefed that because it never came up with
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typicality for Ms. Zher. But again, her claims arise under the same facts, and they arise under the same legal and remedial theories. There is certainly nothing atypical about Ms. Zher who acquired, consumed dangerous amounts of contaminated medicine over many years. She's entirely typical, and there's no surprise to our class definition. And defendants indeed had plenty of opportunity to address that in their papers.

SPECIAL MASTER VANASKIE: All right. Very well.

Thank you.

MS. GEMAN: Thank you.

SPECIAL MASTER VANASKIE: I would not order at this time that CVS -- that plaintiffs be directed to dismiss CVS.

SPECIAL MASTER VANASKIE: I would not order at this time that CVS -- that plaintiffs be directed to dismiss CVS from the medical monitoring complaint, nor do I think it's appropriate to grant leave to file a motion to dismiss on this ground. The matter has been presented now in a couple of letter briefs, and it's clear to me that there is standing on the part of Ms. Zher with respect to a claim against CVS. Whether that holds up in more of a summary judgment type proceeding, I'm not sure, but I don't think it's appropriate at this time to start ticking off individual claims against retail defendants based upon what has been disclosed or not disclosed in the complaint and in the fact sheets, the PFS or in discovery. I think enough has been presented here to at least have a colorable claim on behalf of Ms. Zher against

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SPECIAL MASTER VANASKIE: I understand the concern that you're articulating, but complaints can be amended in a number of ways and even informally and even at trial.
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Document 2142

I'm reluctant to open up pleadings. It seems to me that what has happened here is essentially the -- in the briefs that have been submitted to me, the letter briefs that have been submitted on this issue, the plaintiffs have essentially said that they're amending their complaint to identify Sarah Zher as a class representative for claims against CVS because she purchased contaminated valsartan at CVS. I think in effect you have that. But I can't go beyond that right now.

MS. KAPKE: So is this the last amended complaint that plaintiffs are -- are they going to continue to get opportunities to amend the complaint?

I think that's -- that's what we're searching for here, is a stop to plaintiffs amending the complaints informally.

You know, at some point we are entitled to know the scope of the claims. And that's what I'm trying to get through this procedural issue is some finality to what claims are being asserted.

And so I understand the Court's ruling with respect to Sarah Zher, but I think -- I think we need to figure out if there are any other unasserted, unpleaded claims.

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             I don't want this to come up with another plaintiff
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    down the road that brings up claims against another defendant
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    or other unasserted claims. At some point we have to have
    finality here.
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             SPECIAL MASTER VANASKIE: Well, I understand that you
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    have to have finality, and I think you basically do have
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    finality. You did raise an issue. And the plaintiffs did
    respond to say that you were on notice of the fact that Sarah
 9
    Zher purchased contaminated or allegedly contaminated
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    valsartan at CVS. I think it's fair.
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             MS. KAPKE: Thank you, Your Honor.
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             SPECIAL MASTER VANASKIE: I think that's all we can
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    say on that.
14
             Anything else?
15
             Go ahead, Judge Kugler.
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             THE COURT: Is there anything else?
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             I just want to ask if anybody has any other issues
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    they want to raise at this time with either of us.
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             MR. SLATER: Nothing I'm aware of for the plaintiffs,
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    Your Honor.
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             MR. CARTWRIGHT: Your Honor, I may have one.
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             My name is Daniel Cartwright. I'm with Kenney
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    Shelton Liptak Nowak and I represent the Tops defendants in
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    the Vindigni matter. It originally came out of the Northern
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    District of New York.
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THE COURT: Okay.

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MR. CARTWRIGHT: I just wanted to quickly raise similar issues to the one previous, but we were removed as a defendant in the amended complaint that the Vindignis put in in February. We were just looking for dismissal. I thought we were on for that today, but it appears we may not be. I just wanted to see how we could go about getting ourselves removed from this case and formally dismissed.

I believe we formally either made an application to the Court or requested it, and we were told it would come in the form of an order to show cause.

THE COURT: Well, I -- you have to bring me up to speed.

Why do you think you should be dismissed?

 $$\operatorname{MR.}$ CARTWRIGHT: We were removed as a defendant from the amended complaint.

THE COURT: What do you mean, you were removed as a defendant from? I don't understand what you're talking about, I'm sorry.

MR. CARTWRIGHT: We were not -- meaning that we were named as a defendant, Tops was named as a defendant in the original complaint. And then there was an amended complaint filed February 8, and we were removed as a defendant. We were not named.

THE COURT: You weren't included as a defendant in

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